UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

JUDITH YARRINGTON, ELIZABETH CRAGAN, JULIA CRAIGHEAD and CAROLYN GREEN, individually, and on behalf of all others similarly situated,	:	No.
Plaintiffs,	:	CLASS ACTION COMPLAINT
v.	:	
SOLVAY PHARMACEUTICALS, INC.,	:	JURY TRIAL DEMANDED
Defendant.	:	

CLASS ACTION COMPLAINT

INTRODUCTION

1. This is an action seeking injunctive and monetary relief for Defendant's affirmative misrepresentations that its hormone replacement therapy drug, Estratest, had received approval for marketing by the Federal Food and Drug Administration ("FDA"). Pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.* (the "FDCA"), drug manufacturers must receive pre-approval from the FDA that their drug is safe and effective, before marketing their drugs for "indicated" uses to the public.

2. Estratest and its half-strength version, Estratest H.S. (together "Estratest"), have never been approved by the FDA. Despite the lack of FDA approval, Estratest's manufacturer, Defendant Solvay Pharmaceuticals, Inc.

(herein "Defendant" or "Solvay"), marketed Estratest as being FDA-approved and a suitable prescription for the treatment of moderate to severe physical symptoms associated with menopause when estrogen-only therapy has proven unsuccessful.

3. Thousands of women in the United States who suffer moderate to severe symptoms associated with menopause have been prescribed and purchased Estratest as a result of Defendant's misrepresentations that Estratest is FDA-approved.

JURISDICTION AND VENUE

4. The Court has jurisdiction over this matter and Defendant under 28 U.S.C. § 1332. The amount in controversy exceeds $5,000,000.

5. Venue is proper in this judicial district under 28 U.S.C. § 1391(a) and (c) because Defendant transacts business, committed an illegal or tortious act, has an agent or is found in this district, or because a substantial part of the events described below were carried out in this district.

PLAINTIFF

6. Plaintiff Judith Yarrington is a resident of Hastings, Minnesota and purchased Estratest.

7. Plaintiff Elizabeth Cragan is a resident of Minneapolis, Minnesota and purchased Estratest.

8. Plaintiff Julia Craighead is a resident of Overgaard, Arizona and purchased Estratest.

9. Plaintiff Carolyn Green is a resident of Birmingham, Alabama and purchased Estratest.

DEFENDANT

10. Solvay Pharmaceuticals, Inc. is a corporation organized under the laws of the State of Georgia, with its principal place of business located in Marietta, Georgia. Defendant maintains an office in Baudette, Minnesota.

OPERATIVE FACTS

11. Estrogen is a naturally occurring hormone in women. In the natural course of aging, all women eventually experience a decrease in estrogen production. This usually occurs between the ages of 45 and 55, but may occur earlier or later.

12. The natural decrease and eventual cessation of estrogen production in women is commonly referred to as menopause. As the amount of estrogen in the blood decreases, many women develop typical symptoms such as feelings of warmth in the face, neck, and chest, or sudden intense episodes of heat and sweating throughout the body (*i.e.*, "hot flashes" or "hot flushes"). A few women eventually develop changes in the vagina (called "atrophic vaginitis") which causes discomfort, especially during and after intercourse. In addition, some women may experience nervous symptoms or depression.

13. Estrogens can be prescribed to treat symptoms of menopause.

14. Roughly half of all women undergoing menopause have only mild symptoms or no symptoms at all and rarely seek prescribed estrogens from their

physicians. Other women are prescribed estrogens, while their bodies adjust to lower estrogen levels.

15. Estratest is a drug within the meaning of the FDCA and the regulations of the FDA.

16. Estratest was designed, manufactured, distributed, and sold by Defendant.

17. Defendant expressly stated that Estratest is "indicated" for the management of moderate to severe vasomotor symptoms associated with menopause in patients who do not respond to estrogens alone.

18. Estratest combines esterified estrogens (a type of estrogen) with methyltestosterone (a type of androgen) in one pill. Estratest H.S. tablets contain 0.625 milligrams (mg) of esterified estrogens and 1.25 mg of methyltestosterone. Estratest tablets contain 1.25 mg esterified estrogens and 2.5 mg of methyltestosterone.

19. Pursuant to the FDCA, FDA approval is a prerequisite to the marketing, distribution and sale of a new drug. Estratest is a drug. Estratest requires FDA approval before being marketed and distributed.

20. Estratest has never received FDA approval to be marketed and sold in the United States.

21. From approximately 1964 to early 2009, Defendant marketed, distributed, and sold Estratest throughout the United States.

22. Since 1964, Defendant promoted the misperception that Estratest is FDA-approved when, in fact, it is not.

23. The Physicians' Desk Reference (the "PDR"), is widely acknowledged as the leading reference guide used by physicians for researching and determining which FDA- approved drugs are best prescribed for their patients. The PDR stated that Estratest is indicated for the treatment of moderate to severe vasomotor symptoms associated with menopause in patients not improved by estrogen alone. Yet even doctors such as Steven Ory, who researched this class of drugs (*i.e.*, estrogen-androgen combinations) for the American College of Obstetricians and Gynecologists, reportedly had no idea that Estratest was not FDA-approved. *See* Chris Adams, *FDA Approval Is Still Pending For a Drug in Use Since 1964*, THE WALL STREET JOURNAL, March 20, 2003 (On-line Health). When recently told that Estratest, in fact, was not FDA-approved, Dr. Ory pulled out his PDR and turned to the Estratest listing to support his belief that Estratest was an FDA-approved drug.

24. The PDR publishes the information it receives from drug manufacturers such as Defendant.

25. Defendant had submitted detailed information regarding Estratest to the publishers of the PDR which has in fact been published annually in the PDR for several years – *e.g.*, indications for which the drug is suited for, contraindications, common side effects and adverse reactions, warnings, dosage levels and administration. The information provided by Defendant that is

published in the PDR deceived physicians and consumers into believing that Estratest is an FDA-approved drug.

26. Defendant's website (*i.e.*, www.solvaypharmaceuticals-us.com) – where physicians, consumers and drug salespersons may seek information about Estratest – contained the same misleading information that Defendant had caused to be published in the PDR.

27. Defendant's website, www.solvaypharmaceuticals-us.com.com, posted a downloadable computer file of "prescription" information for Estratest.

28. Misleading information regarding Estratest was also contained on the PDR's consumer website (*i.e.*, www.PDRhealth.com), which contained a listing for Estratest, stating that drugs listed in the PDR are FDA-approved:

> For more than 50 years, doctors have relied upon the Physicians' Desk Reference for the latest, most accurate drug information. Today that trusted knowledge is available to you and your family through PDR*health*.
>
> **The drug information on PDR*health* is written in lay terms and is based on the FDA-approved drug information found in the PDR.** It gives consumers plain-English explanations for the safe and effective use of prescription and nonprescription drugs —explanations that are consistent with the information professionals are referencing in the PDR. Use this section to read about a drug your doctor may have prescribed to check for side effects, drug interactions, and other important information.
>
> [Accessed on Jan. 24, 2004 at http://www.gettingwell.com/drug_info/index.html; emphasis added.]

29. Estratest has never been approved by the FDA for Defendant's claimed indications. In 1972, the FDA approved five estrogen-androgen combination drugs for the indicated treatment of "menopausal symptoms in those patients not improved by estrogen alone." 37 Fed. Reg. 18225. Estratest was not among those drugs approved by the FDA. Nor was Estratest approved by the FDA's 1976 revisions to the 1972 Federal Registrar notice when the indicated treatments for estrogen-androgen combination drugs was changed to "[m]oderate to severe vasomotor symptoms associated with menopause in those patients not improved by estrogen alone."

30. In 1981, Defendant (or its predecessors) submitted a first Abbreviated New Drug Application ("ANDA") seeking FDA approval of Estratest. While Defendant's ANDA was pending FDA approval, Defendant continued to market and sell Estratest. In April 2003, the FDA amended its previous notice to reclassify estrogen-androgen combinations such as Estratest, as "lacking substantial evidence of effectiveness for the treatment of moderate to severe vasomotor symptoms associated with menopause in those patients not improved by estrogen alone." 71 Fed. Reg. 17,953 (Apr. 14, 2003).

31. Defendant knew or should have known that the PDR describes the drugs listed therein as having received FDA approval. Defendant knew or should have known that physicians, consumers and other persons who read the PDR would believe that the drugs listed therein received FDA approval. By taking advantage of physicians' and consumers' reliance on the PDR and PDR*health*,

Defendant continued to spread misinformation regarding Estratest's lack of FDA approval.

32. As a result of Defendant's misleading and deceptive marketing practices, physicians prescribed Estratest to their patients. In addition, thousands of women have purchased a drug they believed to be FDA-approved in accordance with their doctor's prescription. On-line pharmacies regularly touted Estratest as being FDA-approved in comparison to other advertised drugs that are not FDA-approved. Messages posted in on-line "chat rooms" devoted to menopause (*e.g.*, www.hystersisters.com) indicate that its participants believed that Estratest is FDA-approved and that "generic" alternatives to Estratest exist.

33. Despite Defendant's inability to obtain FDA approval for its Estratest product, Defendant continued to market, distribute, and sell Estratest under the false guise of FDA approval. In one striking example, THE WALL STREET JOURNAL reported that "[w]hen [Solvay] filled out a form required to sell the drug to the Defense Department, Defendant checked off that Estratest was FDA-approved. (The company says it was "an inadvertent error.")

34. The benefits to Defendant's promotion of this "inadvertent error" are readily apparent. According to THE WALL STREET JOURNAL, in the past dozen years alone, doctors have written nearly 35 million prescriptions, generating as much as $178 million a year for Estratest's manufacturers. For the year 2000, Estratest was 199th on the list of the top 200 prescription drugs in retail sales.

Sales were roughly $110 million and growing in 2001, according to published reports.

35. Contrary to Defendant's previous marketing message, however, Estratest is not FDA-approved.

36. Estratest was not among the five estrogen/androgen combination treatment therapies approved by the FDA's Federal Register notice published on September 8, 1972. Rather, that notice declared the five estrogen-androgen combination treatments to be safe and effective for (a) the "prevention of post-partum breast engorgement" and (b) the "menopausal symptoms in those patients not improved by estrogen alone." 37 Fed. Reg. 18225.

37. Estratest was also not approved by the FDA's Federal Register notice published on September 29, 1976. The 1976 Register notice revised the FDA's previous 1972 indication for menopausal patients to read:

> Moderate to severe vasomotor symptoms associated with the menopause in those patients not improved by estrogen alone. (There is no evidence that estrogens are effective for nervous symptoms or depression which might occur during menopause, and they should not be used to treat these conditions.) [41 Fed. Reg. 43112, at 43113.]

38. In 1981, the Center for Drug Evaluation and Research determined that the 1976 Register notice could be applied to two additional combination drug products being marketed at the time: (a) conjugated estrogens and methyltestosterone and (b) esterified estrogens and methyltestosterone. Because Estratest fell into the second category of newly noticed drugs, the FDA accepted

for review Reid-Provident Laboratories' (subsequently acquired by Solvay Pharmaceuticals, Inc.) Abbreviated New Drug Application for Estratest and Estratest H.S.

39. From 1993 until 1998, the FDA withdrew its approval of the five new drug applications identified in the 1972 and 1976 notices.

40. On October 29, 1998, Defendant submitted a citizen petition requesting the FDA to determine that the products covered by the applications withdrawn in the 1998 Register notice were not withdrawn for reasons of safety or effectiveness. In the meantime, Defendant continued to manufacture, market, distribute and sell Estratest.

41. On April 14, 2003, the FDA initiated formal proceedings to resolve the question of whether substantial evidence exists to support the effectiveness of estrogen-androgen combination products (such as Estratest) for the treatment of moderate to severe vasomotor symptoms associated with the menopause in those patients not improved by estrogen alone. As described by the FDA:

> The indication for estrogen-androgen combination drug products is limited to that subset of women with "moderate to severe vasomotor symptoms associated with the menopause" that are "not improved by estrogen alone" (emphasis added). The precise wording of the indication quite narrowly defines the intended population. Thus, to be found effective for this narrow indication, there would need to be reliable evidence that estrogen-androgen combination products are effective in treating the population of menopausal women whose vasomotor symptoms are not relieved by estrogen alone. [71 Fed. Reg. 17,955.]

42. The FDA's examination of the data and information that provided the support for the 1976 finding, as well as the subsequent literature, revealed that the FDA's previous determination was unfounded for this indication.

> Clinical studies that evaluated the effect of estrogen-androgen combination therapy specifically on hot flushes found that the combination does not reduce the frequency of vasomotor symptoms more than estrogen alone. […]
>
> Other authors affirm the conclusion that estrogen-androgen combination drug products are not superior to estrogen in reducing vasomotor symptoms (Refs. 3, 20-23). Rosenberg summarized the evidence concerning the alleviation of vasomotor symptoms as follows: "Studies suggest that estrogen is primarily responsible for reductions in vasomotor symptoms and that the addition of androgen neither improves not detracts from this beneficial effect." […]
>
> For the reasons discussed previously, FDA no longer regards combination drug products containing estrogen(s) and androgen(s) as having been shown to be effective for the treatment of moderate to severe vasomotor symptoms associated with the menopause in those patients not improved by estrogen alone. The agency has closely examined the data and information that formed the basis for the 1976 finding that such combinations were effective for this indication, as well as the subsequent literature, and has determined that there is a lack of substantial evidence that this [estrogen-androgen] combination [*i.e.*, Estratest] is effective for "moderate to severe vasomotor symptoms associated with the menopause in those patients not improved by estrogen alone." [71 Fed. Reg. at 17,955.]

43. The evidence supporting the FDA's finding is known by Defendant. Yet, Defendant continued to market and promote Estratest as a FDA-approved drug suitable for moderate to severe physical symptoms associated with women in menopause who are unsuccessful with estrogen only therapies.

44. Plaintiff Yarrington was prescribed Estratest in January 2004 to treat moderate to severe vasomotor symptoms associated with menopause after undergoing a hysterectomy.

45. Plaintiff Yarrington stopped taking Estratest after learning that it was not FDA-approved.

46. Plaintiff Cragan was prescribed Estratest in 1994 to treat moderate to severe vasomotor symptoms associated with menopause after undergoing a hysterectomy.

47. Plaintiff Cragan stopped taking Estratest in 2000 when she learned that it was not FDA-approved.

48. Plaintiff Craighead was prescribed Estratest in 1991 or 1992.

49. Plaintiff Craighead stopped taking Estratest in 2004 when she learned that it was not FDA-approved.

50. Plaintiff Green was prescribed Estratest in 1995.

51. Plaintiff Green stopped taking Estratest in 2004.

CLASS ALLEGATIONS

52. Plaintiffs bring this action on behalf of themselves and all others similarly situated, pursuant to the provisions of Fed. R. Civ. P. 23(a)(1)-(4) and 23(b)(1)-(3), as the Court may determine to be applicable and appropriate, in connection with the proceedings to certify this action and its common questions as a class action. Plaintiffs propose the following class definition, subject to amendment as appropriate:

> All natural persons who purchased Estratest in any state of the United States of America other than the State of California between March 8, 1998 and the present ("the Class Period").
>
> Excluded from the Class are: (1) Solvay, or any of its parent, subsidiary, or affiliate organizations, and the officers, directors, agents, servants, or employees of those organizations, and the members of the immediate family of any such individual or entity; (2) all persons who timely opt out of this proceeding; (3) all claims for personal injury or wrongful death arising from the ingestion of Estratest; (4) Plaintiffs' attorneys and the members of their immediate families; and (5) the judge to whom this case is assigned, and any member of the judge's immediate family.

53. Alternatively, should it be found that any of Plaintiffs' state law claims could not be certified on a national basis, Plaintiffs seek statewide subclasses (or groups of statewide subclasses) for these same persons.

54. While the exact size of the Class is unknown to Plaintiffs at present, the members of the Class are numerous and geographically dispersed throughout the United States and joinder is impracticable.

55. Plaintiffs' claims are typical of those of the members of the Class, in that Plaintiffs and the members of the Class purchased Estratest within the Class Period. The types of damages incurred by Plaintiffs are similar to those incurred by members of the Class. The claims of the Class are co-extensive and may materially vary only in the degree of damages. Plaintiffs' claims arise from the same uniform course of conduct by Defendant and are based upon the same legal theories as the claims of all.

56. Plaintiffs will fairly, adequately, and vigorously represent and protect the interests of the Class

57. The interests of Plaintiffs coincide with, and are not antagonistic to, those of the Class.

58. In addition, Plaintiffs' counsel are experienced and competent in the prosecution of complex class action litigation.

59. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual members.

60. Questions of law and fact common to the Class include, but are not limited to:

a. whether Defendant designed, manufactured, distributed and sold Estratest;

b. whether Solvay made deceptive statements and/or omissions to Plaintiffs and the Class in connection with the marketing, solicitation and sale of Estratest;

c. whether through its distributors, agents and/or promotional literature, Solvay's actions were likely to cause confusion or misunderstanding as to Estratest's lack of FDA approval.

d. whether Solvay violated the Minnesota Unlawful Trade Practices Act, Minn. Stat. § 325D.09 et seq., or similar statutes of all other states (except California);

e. whether Solvay violated the Minnesota Deceptive Trade Practices Act, Minn. Stat. § 325D.43 et seq., or similar statutes of all other states (except California);

f. whether Solvay violated the Minnesota False Statement in Advertising Act, Minn. Stat. § 325F.67, or similar statutes of all other states (except California);

g. whether Solvay violated the Minnesota Consumer Fraud Act, Minn. Stat. § 325F.68 et seq., or similar statutes of all other states (except California);

h. whether the Class was injured and should recover damages;

i. whether Solvay should be enjoined from misrepresenting the true nature of Estratest's regulatory status; and

j. whether Defendant should be ordered to make restitution to the named Plaintiffs and members of the Class.

61. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Among other things, class action treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress

for claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

62. Defendant has acted or refused to act on grounds that apply generally to the Class, making final injunctive, equitable, or declaratory relief appropriate. Class treatment is also appropriate to provide consistent adjudication of common issues to ensure compatible standards of conduct for Defendant, and to ensure fair and consistent treatment of the interests of the Class.

63. Plaintiffs know of no difficulty to be encountered in litigation of this action that would preclude its maintenance as a class action.

COUNT I
MINNESOTA PREVENTION OF CONSUMER FRAUD ACT
MINN. STAT. § 325F.68, ET SEQ.

64. The allegations set forth in each of the preceding paragraphs are incorporated by reference as if fully set forth herein.

65. Minn. Stat. § 325F.69, subd. 1, provides:

> The act, use, or employment by any person of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby, is enjoinable as provided in section 325F.70.

66. Defendant misrepresented to Plaintiffs and the Class that Estratest was FDA-approved for Defendant's indicated uses. Defendant has engaged in deceptive and fraudulent practices, and made false and misleading statements,

with the intent that Plaintiffs and the Class rely on them in connection with the sale of Estratest.

67. Defendant's conduct described herein constitutes multiple, separate violations of Minn. Stat. § 325F.69, subd. 1. By failing to disclose and omitting material facts, Defendant has engaged in deceptive and fraudulent practices in violation of the Consumer Fraud Act, and has damaged Plaintiffs and members of the Class.

COUNT II
MINNESOTA UNLAWFUL TRADE PRACTICES ACT
MINN. STAT. § 325D.09, ET. SEQ.

68. The allegations set forth in each of the preceding paragraphs are incorporated by reference as if fully set forth herein.

69. Minn. Stat. § 325D.13 provides:

> No person shall, in connection with the sale of merchandise, knowingly misrepresent, directly or indirectly, the true quality, ingredients or origin of such merchandise.

70. Whether a drug is FDA-approved, and is therefore suitable for marketing, distribution, and sale, is a "quality" within the meaning of Minn. Stat. § 325D.13.

71. Through its distributors, agents and promotional literature, Defendant has used this quality to mislead Plaintiffs and the Class about Estratest's regulatory status. Estratest had never been FDA-approved for any of the purposes indicated by Defendant.

72. Defendant knowingly misrepresented this quality at the time Plaintiffs and the Class purchased Estratest.

73. Defendant's conduct described herein constitutes multiple, separate violations of Minn. Stat. § 325D.13. By failing to disclose and omitting material facts, Defendant has engaged in deceptive and fraudulent practices in violation of the Unlawful Trade Practices Act, and has damaged Plaintiffs and members of the Class.

COUNT III
MINNESOTA DECEPTIVE TRADE PRACTICES ACT
MINN. STAT. § 325D.43

74. The allegations set forth in each of the preceding paragraphs are incorporated by reference as if fully set forth herein.

75. Minn. Stat. § 325D.44, subd. 1 provides, in part:

> A person engages in a deceptive trade practice when, in the course of business, vocation, or occupation, the person; . . .
>
> (2) causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
>
> (3) causes likelihood of confusion or of misunderstanding as to affiliation, connection, or association with, or certification by, another; . . .
>
> (5) represents that goods or services have . . . characteristics . . . benefits . . . that they do not have; . . .
> (7) represents that goods or services are of a particular standard, quality, or grade . . . if they are of another; . . .

> (9) advertises goods or services with intent not to sell them as advertised; . . .
>
> (13) engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.

76. Defendant designs, manufactures, distributes and sells Estratest.

77. Through its distributors, agents and promotional literature, Defendant represented that Estratest was FDA-approved, and therefore suitable for marketing, distribution and sale. Defendant further indicated that Estratest was suitable for the treatment of the symptoms of menopause.

78. In fact, however, Estratest has never been approved by the FDA.

79. Defendant's actions were likely to cause confusion or misunderstanding as to the source, sponsorship, approval, or certification of Estratest.

80. Defendant's actions were likely to cause confusion or misunderstanding as to affiliation, connection, or association with, or certification by the FDA.

81. Defendant used the afore-described deceptive representation in connection with its design, manufacture, distribution and sale of Estratest.

82. Defendant misrepresented that Estratest has sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that it does not have.

83. Defendant misrepresented that Estratest is of a particular standard, quality, or grade.

84. Defendant advertised Estratest with the intent not to sell it as advertised.

85. Defendant's conduct described above constitutes multiple, separate violations of Minn. Stat. § 325D.44, subd. 1. In failing to disclose and omitting material facts, Defendant has engaged in deceptive and fraudulent practices in violation of the Uniform Deceptive Trade Practices Act, and has damaged Plaintiff and members of the Class.

COUNT IV
MINNESOTA FALSE STATEMENTS IN ADVERTISING ACT
MINN. STAT. § 325F.67

86. The allegations set forth in each of the preceding paragraphs are incorporated by reference as if fully set forth herein.

87. Minn. Stat. § 325F.67, in pertinent part, provides:

> Any person, firm, corporation, or association who, with intent to sell or in anywise dispose of merchandise, securities, service, or anything offered by such person, firm, corporation, or association, directly or indirectly, to the public, for sale or distribution, or with intent to increase the consumption thereof, or to induce the public in any manner to enter into any obligation relating thereto, or to acquire title thereto, or any interest therein, makes, publishes, disseminates, circulates, or places before the public, or causes, directly or indirectly, to be made, published, disseminated, circulated, or placed before the public, in this state, in a newspaper or other publication, or in the form of a book, notice, handbill, poster, bill, label, price tag, circular, pamphlet, program, or letter, or over any radio or television station, or in any other way, an advertisement of any sort regarding merchandise, securities, service, or anything so offered to the public for use, consumption, purchase, or sale, which

> advertisement contains any material assertion, representation, or statement of fact which is untrue, deceptive, or misleading, shall, whether or not pecuniary or other specific damage to any person occurs as a direct result thereof, be guilty of a misdemeanor, and any such act is declared to be a public nuisance and may be enjoined as such.

88. Defendant intended to induce the Plaintiffs and the Class to purchase Estratest.

89. Defendant sought to achieve this goal by publishing, disseminating, circulating, and otherwise placing before the public of Minnesota, advertisements relating to the availability, consumption and/or sale of Estratest.

90. Such advertisements relating to the availability, consumption and/or sale of Estratest contained a material falsehood, were deceptive and otherwise misleading. These advertisements misrepresented that Estratest had been FDA-approved for Defendant's indicated uses of Estratest.

91. Defendant's conduct described above constitutes multiple, separate violations of Minn. Stat. § 325F.67. Defendant has made public statements that are untrue, deceptive, and misleading, with intent to sell or increase the consumption of services. In failing to disclose and omitting material facts, Defendant has further made deceptive and fraudulent public statements in violation of the False Statements in Advertising Act, and has damaged Plaintiff and members of the Class.

COUNT V
UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION VIOLATIONS UNDER THE LAWS OF ALL OTHER STATES (EXCEPT CALIFORNIA)

92. The allegations set forth in each of the preceding paragraphs are incorporated by reference as if fully set forth herein.

93. Should the unfair trade practices and consumer protection laws of Minnesota not be applicable to Plaintiff and Class members, as pled above, Plaintiffs assert a claim for Class members for damages under the unfair trade practices and/or consumer protection statutes of all other states (except California), specifically including the following statutes:

Alabama

Ala. Code §§ 8-19-1 to 8-19-15

Alaska

Alaska Stat. §§ 45.50.471 to 45.50.561
Alaska Admin. Code 9 §§ 05.010-05.900

Arizona

Ariz. Rev. Stat. Ann. §§ 44-1521 to 44-1534

Arkansas

Ark. Code Ann. §§ 4-88-101 to 4-88-115

Colorado

Colo. Rev. Stat. Ann. §§ 6-1-101 to 6-1-115

Connecticut

Conn. Gen. Stat. Ann. §§ 42-110a to 42-110q

Delaware

Del. Code Ann. 6 § 2511-2527
Del. Code Ann. 6 § 2531-2536

Florida

Fla. Stat. Ann. §§ 501.201-501.213

Georgia

Ga. Code Ann. §§ 10-1-370 to 10-1-375
Ga. Code Ann. §§ 10-1-390 to 10-1-407

Hawaii

Haw. Rev. Stat. §§ 481A-1 to 5

Idaho

Idaho Code Ann. §§ 48-601 to 48-619

Illinois

815 Ill. Comp. Stat. Ann. 505/1-505/12
815 Ill. Comp. Stat. Ann. 510/1-510/7

Indiana

Ind. Code §§ 24-5-0.5-1 to 24-5-0.5-12

Iowa

Iowa Code Ann. § 714.16

Kansas

Kan. Stat. Ann. § 21-4403
Kan. Stat. Ann. §§ 50-623 to 50-639

Kentucky

Ky. Rev. Stat. Ann. §§ 367.110 to 367.360

Louisiana

La. Rev. Stat. Ann. §§ 51:1401 to 51:1426
La. Rev. Stat. Ann. §§ 51.411 to 51:414

Maine

Me. Rev. Stat. Ann. 10 §§ 1211-1216

Me. Rev. Stat. Ann. 5 §§ 205-A-214

Maryland

Md. Code Ann. Com. Law §§ 13-301 to 13-319

Massachusetts

Mass. Gen. Laws Ch. 93A §§ 1-11

Michigan

Mich. Comp. Laws §§ 445.901-445.922
Mich. Comp. Laws §§ 445.351-445.364

Mississippi

Miss. Code Ann. §§ 75-24-1 to 75-24-27

Missouri

Mo. Ann. Stat. §§ 407.010 to 407.130

Montana

Mont. Code Ann. §§ 30-14-101 to 224

Nebraska

Neb. Rev. Stat. §§ 87-301 to 306

Nevada

Nev. Rev. Stat. Ann. §§ 598.0903 to 598.0925

New Hampshire

N.H. Rev. Stat. Ann. §§ 358-A:1 to 358-A:13

New Jersey

N.J. Stat. Ann. §§ 56:8-1 to 56:8-184

New Mexico

N.M. Stat. Ann. §§ 57-12-1 to 57-12-26

New York

N.Y. Gen. Bus. Law §§ 349-350-f-1

North Carolina

N.C. Gen. Stat. Ann. §§ 75-1.1 to 75-42

North Dakota

N.D. Cent. Code §§ 51-12-01 to 51-12-15
N.D. Cent. Code §§ 51-15-01 to 51-15-11

Ohio

Ohio Rev. Code Ann. §§ 1345.01 to 1345.13

Oklahoma

Okla. Stat. Ann. 15 §§ 751 to 765

Oregon

Or. Rev. Stat. §§ 646.605 to 656

Pennsylvania

Pa. Stat. Ann. 73 §§ 201-1 to 201-9.3

Rhode Island

R.I. Gen. Laws §§ 6-13.1-1 to 6-13.1-12

South Carolina

S.C. Code Ann. §§ 39-5-10 to 39-5-170

South Dakota

S.D. Codified Laws §§ 37-24-1 to 37-24-48

Tennessee

Tenn. Code Ann. §§ 47-18-101 to 47-18-129

Texas

Tex. Bus. & Com. §§ 17.41 to 17.506

Utah

Utah Code Ann. §§ 13-11a-1 to 13-11a-5

Vermont

Vt. Stat. Ann. 9 §§ 2451 to 2466a

Virginia

Va. Code Ann. §§ 59.1-196 to 59.1-207

Washington

Wash. Rev. Code Ann. §§ 19.86.010 to 19.86.920

West Virginia

W. Va. Code Ann. §§ 46A-6-101 to 46A-6-110

Wisconsin

Wis. Stat. Ann. § 100.18

Wyoming

Wyo. Stat. Ann. §§ 40-12-101 to 40-12-114

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendant and for the following relief:

(a) That the Court determine that this action may be maintained as a class action pursuant to the appropriate provisions and sections of Rule 23(b)(3) of the Federal Rules of Civil Procedure;

(b) Judgment against Defendant in favor of Plaintiffs and members of the Class for all relief permitted by law, including all applicable actual, multiple, and punitive or exemplary damages, the costs of this suit, pre- and post-judgment interest at the legally allowed limit, reasonable costs and attorney fees, as allowed by law, and/or from the common fund and for all costs associated with administration of the common fund;

(c) Disgorgement of Defendant's revenues or profits gained from their misconduct, including restitution to Plaintiffs and members of the Class;

(d) That the Court grant Plaintiffs and members of the Class equitable and/or injunctive relief; and

(e) That the Court grant Plaintiffs and members of the Class such other, further, and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury on all claims so triable.

Dated: August 27, 2009

Respectfully submitted,

By: s/ Daniel E. Gustafson
Daniel E. Gustafson (#202241)
Karla M. Gluek (#238399)
Brian L. Williams (#23249X)
GUSTAFSON GLUEK PLLC
608 Second Avenue South
650 Northstar East
Minneapolis, MN 55402
Telephone: (612) 333-8844
Facsimile: (612) 339-6622

Elizabeth A. Alexander
LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP
One Nashville Place
150 Fourth Avenue, N., Suite 1650
Nashville, TN 37219
Telephone: (615) 313-9000
Facsimile: (615) 313-9965

Richard M. Heimann
Michael W. Sobol
LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP
Embarcadero Center West
275 Battery Street, 30th Floor
San Francisco, CA 94111-3339
Telephone: (415) 956-1000
Facsimile: (415) 956-1008

Attorneys for Plaintiffs